Blinking Orbital Prosthesis

Client: Gregory G. Gion, MMS, CCA

Advisor: Professor Thomas Yen, PhD

Leader: Bret Olson

Communicator: Justin Cacciatore

BWIG: Michael Konrath

BSAC: Blake Marzella

Table of Contents

Abstract

At the Medical Art Prosthetics Clinic in Madison, Greg Gion and his associates make prosthetics for those who have lost their eyes due to an accident, disease, or genetic disorder. Mr. Gion's goal is to help the thousands of people who have an absence of facial tissue by restoring their appearance and giving them greater self confidence. The problem with the current prosthetics is that they are completely static, which makes them quite noticeable to the casual observer. Our goal for this project is to create a prosthetic eye that has the ability to blink, and therefore enhances the realism of the prosthesis as a whole. Through our research, we were able to incorporate the function of the actual human eye muscles and a few existing designs to develop an effective prototype.

Introduction

A prosthetic is a medically fabricated device that serves as an extension or replacement of a damaged body part in order to restore functionality and provide the user with a more natural appearance[1]. In the event where an individual experiences the loss or surgical removal of an eye due to an injury, genetic defect, or disease, the use of an orbital prosthesis restores the individual's natural appearance (Figure 1). However, while the current orbital prosthetics promote an overall sense of restoration and realism, the prosthetics lack the ability to simulate a human blink. It is this static nature which prevents an orbital device from completely restoring an individual's appearance. We intend to design a mechanism that will allow for an orbital prosthetic to blink in order to provide the appearance of functionality of a natural eye in conjunction with the already realistic static appearance.

Figure 1: Actual Medical Arts Prosthetics Clinic Patient http://www.medicalartprosthetics.com

Background

The development of an orbital prosthesis is regarded as both an art and a science, referred to as anaplastology[2]. Each prosthesis must be custom made in order to provide the most realistic and life-like appearance. As such, variances such as the individual's skin tone, direction of skin folds, skin texture, facial proportions and anatomical landmarks must all be taken into consideration[2]. The overall surface area of the prosthesis must also be taken into consideration. For example, some individuals may experience the surgical removal of larger regions than just the eye; regions such as the eyebrow, portions of the nose as well as parts of one's cheek[1]. As a result, an orbital prosthesis may include extensions to satisfy these areas, affecting the aesthetic appearance. Great artistic skill is required in order to provide a prosthesis that smoothly transitions from the organic tissue to the prosthetic material. These skills also aid in the development of the prosthetic eye which must match its real equivalent in size, shape, shading, and coloration. In order to satisfy the need for a natural prosthesis, these devices are commonly made out of PMMA, or poly methyl methacrylate, and acrylic[1]. The PMMA composes the fleshy portions of the prosthesis while the eye is composed of acrylic. A prosthesis typically lasts an individual for upwards of two years and commonly needs to be replaced due to color degradation and user wear and tear. Consistent cleaning and maintenance as well as the use of sunglasses to slow the color degradation from UV radiation exposure can extend the life of an orbital prosthesis [2].

Figure 2: Development of realistic prosthetic eye
http://www.medicalartprosthetics.com

The making of an individual prosthesis commonly begins by taking molded impressions of the empty orbital cavity. This is done in order to accurately record the anatomical features of the cavity which provide the basis for the development of the prosthesis [2]. From this mold, a wax prototype is created and sculpted. This is done in the presence of the patient in order to integrate the patient's opinion into the prosthetic's development[1]. Once a wax prototype is accurately made which satisfies the client's needs, pictures are taken of the client's skin surrounding the orbital cavity in order to assist in the development of prosthesis' color tone. At this point, a prosthesis is made out of PMMA and acrylic and placed on the client. Here, meticulous details such as freckles, blood vessels in the eye, hair, and the skin folds are made by hand to help provide a more natural transition from the surrounding tissue to the prosthetic material [1] (Figure 2). From this, the final prosthesis is made and delivered to the client.

Problem Statement

People of any age or gender may experience the surgical removal of an eye due to an injury, genetic defect, or disease. The use of an orbital prosthetic allows these individuals to gain a sense of self-confidence and a more positive self-image. However, while prosthetics have been developed to create an incredibly realistic and aesthetically pleasing orbital device, they have failed to provide the appearance of functionality of a real eye. That is, the prosthetics are static and cannot blink. This is illustrated in Figure 3 as the eyelids of the prosthetic remain in the same position even when the eye is removed. Our client desires for us to devise a mechanism which would allow for a prosthetic eye to blink. This mechanism will be used as a model in presentations to illustrate the blinking mechanism's effectiveness and potential for further development. As such, our design does not have to meet the requirements for direct use for a client. However, we intend to expand upon our client's original goal and look forward toward the implementation of our mechanism into an actual orbital device. That is, we aim to meet some of the basic requirements for function in an actual orbital prosthesis through the development of our blinking mechanism. It is our hope that by doing so, our blinking mechanism can easily transform from a working theory to the actual implementation of our design for an individual's use in a prosthetic. Only by developing a mechanism through which an orbital prosthesis can blink can the steps toward developing a complete orbital prosthesis, one that includes both a natural appearance and the appearance of functionality, be undertaken.

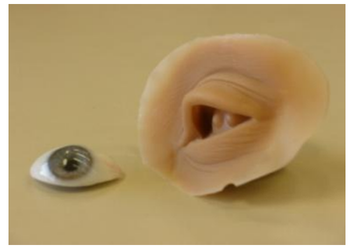

Figure 3: Current prosthetic eye, showing the acrylic eyepiece and PMMA material separately.

Problem Overview

In order to provide individuals who have undergone the total surgical removal of an eye a complete orbital prosthesis, we intend to develop a mechanism which would allow a prosthetic eye to blink. Our client's main focus is to develop a mechanism that can be used in presentations to demonstrate our design's potential for further development. However, we are taking into consideration the constraints and environment our mechanism would be exposed to should it be developed into an actual prosthesis. We hope that by doing so, we can facilitate a smoother transition from a presentation model to an implantable blinking prosthetic eye. In order to create such a mechanism, it is imperative that we research the blinking mechanism of a normal human eye. Our mechanism must be able to successfully recreate both the normal blink of a human eye and its consistent performance throughout the day. We must also consider how our mechanism is to be powered and how this power option could the affect the development of a later prosthetic prototype.

Problem Motivation

People who experience damage to an eye due to trauma, birth defect or disease have two options considering an orbital prosthesis. If only the eye is damaged, an ocular prosthesis is used. However, if there is damage to the surrounding area, such as the eye lids or orbit, an orbital prosthesis must be used. Patients who receive an orbital prosthesis do so to retain a normal appearance. Ideally, these patients could live their lives and the people they encounter on a daily basis would never know they had a prosthetic orbital device [1]. Anaplastolgists are able to create a prosthesis that looks nearly identical to a human eye. However, there are factors that limit the realism of their creations. One of those limitations is the prosthetic's static nature. No matter how realistic a prosthesis looks, it may become noticeable when the prosthetic eye fails to blink. Our motivation for this project is to give back a sense of normalcy to these patients.

Design Constraints

There are essentially two sets of constraints for our design project. The first set of constraints concerns our final goal of creating an implantable blinking orbital prosthesis. Though this is not our primary goal, we are designing our device with these final constraints in mind. Most obviously, the eye must be able to blink. It must also be able to do so at a speed as close as possible to the actual speed of a blink, a rate of 200-300 milliseconds per blink. Since this would actually be implanted into a person, there are size constraints. Each prosthesis is a different size depending on the patient, so this design would need to fit in about the size of the human eyeball, which has a diameter of about 25-29mm in order to accommodate all of them. The prosthesis would have to be comfortable for the patients to wear on a nearly daily basis. This means the design would have to be silent, not produce vibrations and relatively lightweight, all of which would be bothersome for the patient. Most importantly, the design would have to be safe. There would have to be no chance of electrical shock. Materials used would have to be bio-compatible and non-allergenic and the prosthesis would need to be easily sanitized to avoid complications such as infection. Current orbital prostheses already need to be replaced occasionally due to growth of the patient or wear [1]. Ideally this design would last as long as the rest of the prosthesis. We decided that a lifetime of a year, with only minor maintenance, would be reasonable. To achieve maximum realism, the prosthesis would need to blink synchronized with the real eye. It would also need to do so reliably without failure.

Our primary set of constraints concerns the creation of a model to be used for demonstrations. Therefore, these constraints focus only on the mechanical aspects of our blinking mechanism. Our model will have to be able to blink upon request. If the demonstration fails even once or breaks, the quality of the design will be questioned. Our design must also be safe for the demonstrator to use. We will also be trying to keep our design as small and fast as possible.

Current Devices

Currently, there are no blinking orbital prostheses on the market due to the fact that current orbital prostheses are completely static. There are many different ways that the current static prostheses can be attached. Osseointegration is one such attachment process where the prosthesis is surgically attached to the bone of the patient. Another is the use of a pair of magnets that can be attached to the bone as well as the prosthesis. Finally, the prosthesis can just be attached using adhesives[1].

Our group took inspiration from current devices which aid in the blinking function of patients with intact eyes. These devices are used to help patients with muscle paralysis, a condition that prevents these individuals from blinking normally. This is done for cosmetic, but more importantly, functional purposes as well. Since the patients still has a working eye, they still need to blink in order to lubricate the eye. Our blinking orbital prosthesis would only need to blink for cosmetic reasons as an artificial eye would have no need for lubrication. The technique that is most similar to our project is research being done using EPAM (electroactive polymer artificial muscle). Researchers in California have been working on using EPAM to close the eyelid and the use of sling to open the eyelid. At least one patient has had this EPAM technology successfully implanted [3],[4]. Another device called the Arion sling has been used in the past to treat ptosis, a condition occurring when the eyelid sags lower than it should [5]. Other methods, which are used to treat paralytic lagophthalmos, include the use of implantable gold weights and palpebral springs. Gold weights, which are used much more commonly, are jgold implants that weigh the eyelid down due to gravity, but are light enough where the patient can still open their eyelid using their own muscles. Palpebral springs work in a similar fashion, only instead of relying on gravity, the force of a torsion spring closes the eye. The palpebral spring is rarely used as it is more invasive than the gold weight implant, but is favored by some since it doesn't depend on gravity [6]. While these designs aren't used in orbital prostheses, there is some potential for the incorporation of these concepts into the development of our blinking mechanism.

Competition

While there are is no current blinking orbital prosthesis, there is still competition for our design. That competition is the current non-blinking orbital prosthesis. Even though the patients who use an orbital prosthesis do so for realism, they may not always want a more realistic blinking prosthesis for a few reasons. The biggest reason would be cost. A blinking orbital prosthesis will always be more expensive than a non-blinking orbital prosthesis since the blinking prosthesis would contain all of the same parts as the non-blinking prosthesis as well as the parts of the additional blinking apparatus. Therefore, it is important for us to keep costs low enough to where it would be reasonable for a significant portion of the candidates to choose a blinking prosthesis over the static one.

The comfort constraint plays an important role here, as any noise, vibration or weight problems would give the patient a reason to not want a blinking prosthesis. Also, our design would potentially require additional maintenance, such as routine battery changes and mechanics servicing. We must always consider the balance of the added benefits of a blinking orbital prosthesis with any extra hassle it may bring to the user.

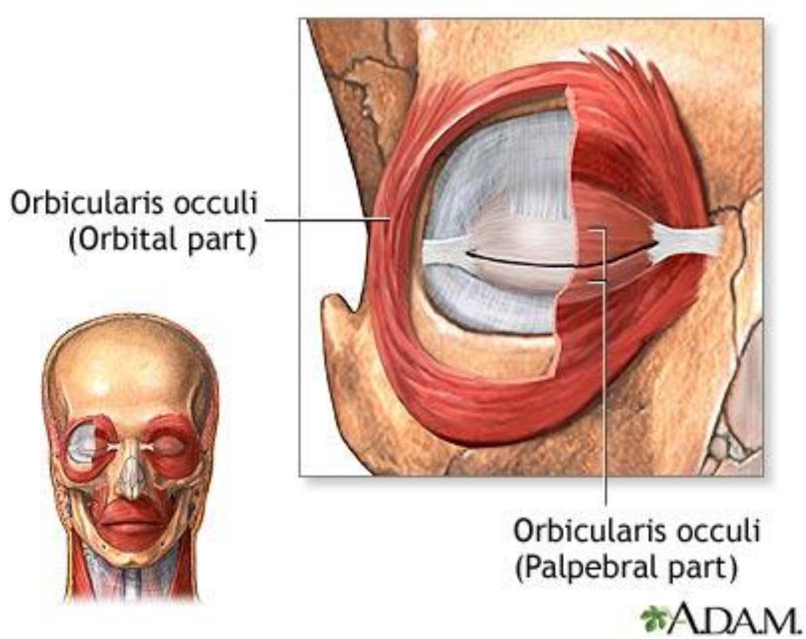

Figure 4: Eye muscle anatomy; highlighting the Orbicularis occuli muscles
http://lomalindahealth.org

Potential Designs

The first two of our three preliminary designs (*servo &*

memory shape), and possibly the third (*EPAM*) use the same machinery to force the prosthetic eye to blink. The designs differ only in the way that they are powered. We call this shared method the *embedded cord tension mechanism.*

Embedded Cord Tension Mechanism

We tried to incorporate our study of the anatomy and function of the actual human eye muscles as inspiration for this mechanism. The orbicularis occuli is the sphincter muscle that surrounds each eye and causes it to blink, both voluntarily and involuntarily[7]. The orbicularis occuli is the system of donut-shaped muscles, the innermost of which extends from a fixed point at the corner of eye, continues through the eyelid, and connects to a fixed point at the other corner (Figure 4). When these muscles contract, they want to span the shortest possible distance between the fixed points and due to the geometry of the eyeball the shortest distance is the closed position. In other words, when you want to close your eyes a message is sent via electrical impulses from your brain to these orbicularis occuli muscles which, in turn shorten, causing the upper eyelid to come down upon the lower one. The orbicularis occuli muscles act in direct opposition to the levator

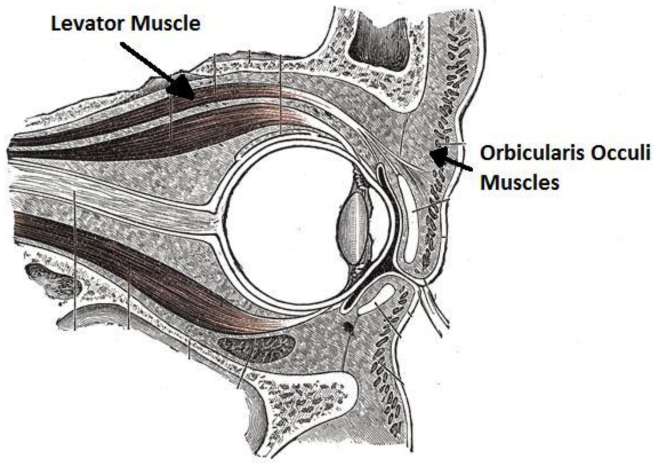

Figure 5: Eye muscle anatomy; highlighting the Orbicularis occuli and levator muscles
http://en.academic.ru

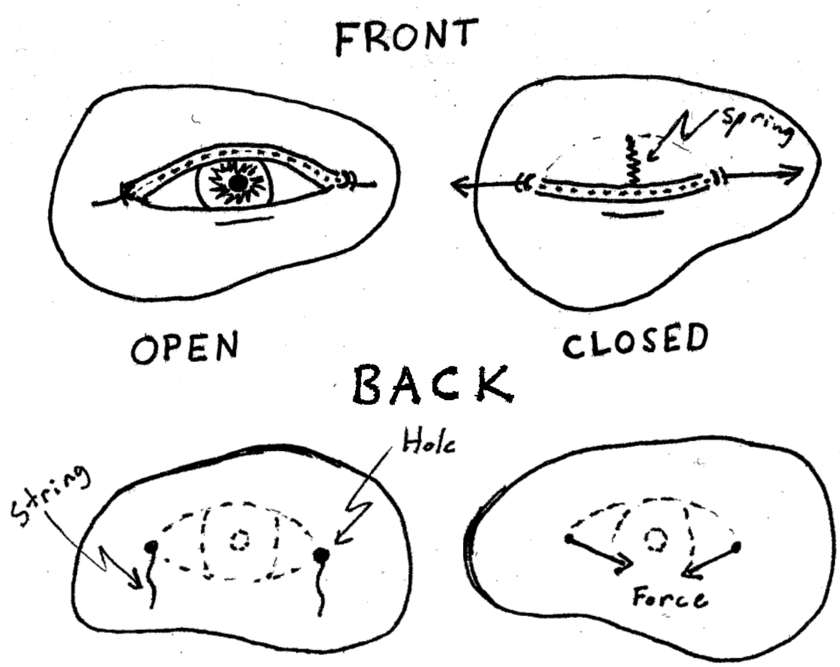

Figure 6: Embedded cord tension mechanism; viewed from both the front and the back

muscle (Figure 5) which pulls the eye back open after a blink has been completed[7].

Our mechanism imitates these companion muscles using a thin plastic string, the Poly(methyl methacrylate) or PMMA of the current prosthetics, and a simple coil spring. We intend to form a piece of the PMMA material into the shape of the opening of the eye; the piece will have both an upper and lower lid. We would then bore a tiny hole into the upper lid and run a thin plastic cord through it. The lids would then be placed over the acrylic, prosthetic eyeball and fixed at the corners of the eye as shown in Figure 6. The thin string embedded in the PMMA is fixed by an inflexible, stabilizing strap. The positions of the straps are crucial. They must be placed in such a position so that when the strings are pulled at the sides the upper eyelid will be forced to come down upon the lower one. This position will be slightly below the level of the lower eyelid and also located on the same hemisphere as the model eyeball. The action created by pulling the strings mimics movement of the orbicularis occuli in the actual eye. The levator muscle action is reproduced by the spring. The spring will be attached to the upper eyelid at the midpoint between the stabilizing straps. It is positioned here so that after the strings do work to bring the eye the down the spring force will immediately bring the upper eyelid back to its initial position, thus completing the blink. Now, our focus turns to how to get tension on the cord in order to initiate the blink.

Micro Servo Motor

Our first design alternative incorporates a micro servo motor (Figure 7). A servo is an automatic device that uses error-sensing feedback to correct its own performance[8]. We intend to use a miniature servo motor (on the order of 50x50x50mm) to create tension on the aforementioned cords.

Figure 7: Micro Servo Motor. Model: GWS Naro+D Micro Digital Servo Motor
http://www.robotshop.ca

The micro servo motor would be located on the side opposite the eyelids in the cavity of the eyeball. Here, it would be fixed by metal supports so that it remained stationary while it worked. The cords would then be attached to the mechanical arm of the servo, so that when

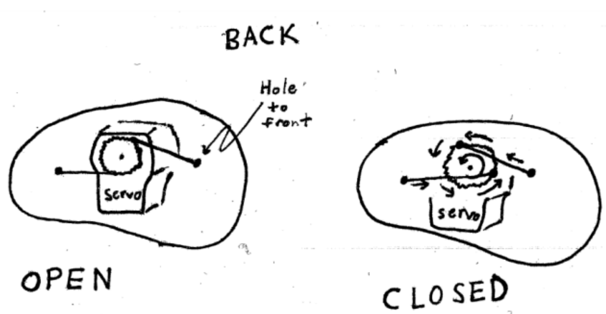

Figure 8: Drawing of the embedded cord tension mechanism powered by a micro servo

the arm is spun, the cords are pulled, and the eye blinks (Figure 8). The ability of the servo to control and sense its own position is very important because it allows us to program the motor to pull the cords just far enough to create a realistic blink and then stop without delay. This feature prevents any damage to the *embedded cord tension mechanism* that could be caused by excessive pulling. Some more advantages of the micro servo include that it has proven to be quick, and strong relative to its small size. For example, a specific Futaba servo rotates a speed of 60 degrees per 0.19 seconds and generates a torque of 4.1 kg*cm[9]. Another positive feature of the servo motor is that it can be easily controlled by a remote, which is essential to our model design because the presenter will not be able to gain access to the cavity of the eye while presenting. The final, but maybe the most important benefit of using a micro servo motor to power our mechanism is that servo motors have a long history and are part of a highly developed market. This makes them easily obtainable, affordable, and guarantees that there will be plenty of individuals with servo expertise to help us should we run into problems during assembly or testing. Some concerns facing this design are noise and bulkiness. Both of these problems have the possibility of causing the patient discomfort while using our device.

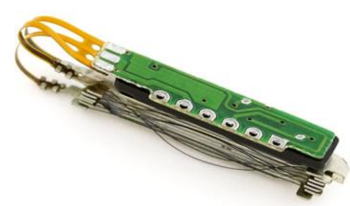

Figure 9: Shape memory alloy actuator. http://www.sparkfun.com

Memory Shape Alloy

Our second design incorporates a memory shape alloy actuator (Figure 9). The memory shape material is a copper-based, Nickel-Titanium alloy. The alloy is able to change shape when an electric current is applied to it. The unique property of this alloy is that it is able to transform into pre-memorized shapes when a specific current is applied to it[10]. We would fix this actuator in the cavity of the eyeball and then attach the cords to both ends. Thus, when the motor contracts, the strings are pulled and the eye closes (Figure 10). The benefits of using a motor that incorporates this memory shape alloy is that it is silent, small (less than 7cm long),weighs just over a gram and can be run from a remote-control. These properties fit into our project well because we are working in

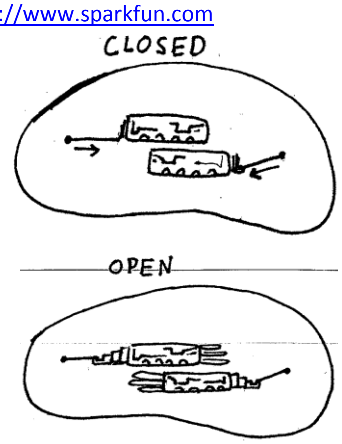

Figure 10: Memory shape alloy actuator drawing.

such a small place and we also want to minimize any discomfort that weight or noise could cause the user. Some problems with this design include that the memory shape alloy motor has a relatively short life cycle of only about 1,000,000 contractions which would only allow the patient to use it for about a month, before it would need to be replaced[11]. It also remains to be seen, if the motor will have enough power to pull the strings far enough to simulate a blink.

Artificial Muscles (EPAM)

The focus of our third design centers on a new technology called artificial muscles or EPAM, which stands for electroactive polymer artificial muscle. Artificial muscles consist of a thin layer of dielectric polymer film between two conductive, compliant electrodes. When a voltage is applied to these electrodes, the positive and negative charges of the electrodes attract each other. This causes the polymer to contract in thickness and expand in area because the polymer as a whole is incompressible. By attaching materials to direct this motion into the desired axis, an EPAM actuator is created that can effectively mimic the muscle movements of living organisms.[12]

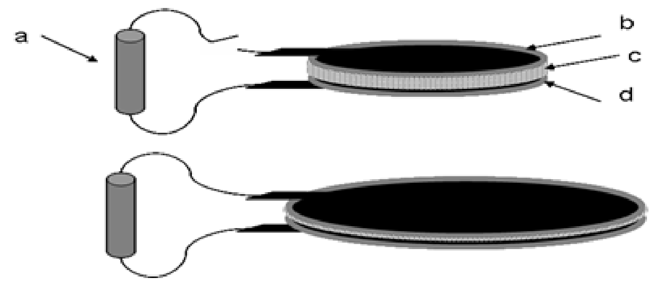

Figure 11: Basic function of EPAM device
http://www.artificalmuscles.com

Benefits of artificial muscle include that it is fast, completely silent, strong, achieving actuation pressures up to 1.9 MPa, and able to contract a large distance relative to its length, having strain values greater than 30%.[13] Artificial muscles can also be very small, "allowing designs that may achieve the size and forms of geckos, hummingbirds and cockroaches." [14] All of these attributes make them ideal as a power source for our *embedded cord tension mechanism.* In this case, a small EPAM actuator would be fixed behind the acrylic artificial eye piece, each end attached to one of the strings of the *embedded cord tension mechanism*. When the EPAM actuator would contract, it would pull both strings and activate

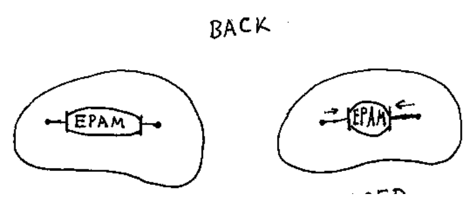

Figure 12: Embedded cord tension mechanism powered by EPAM.

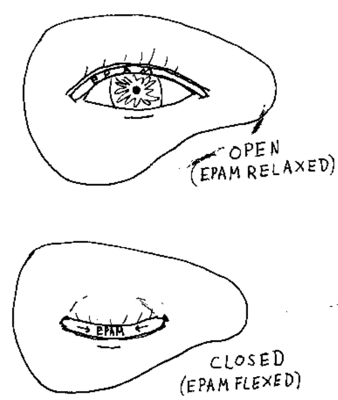

Figure 13: Drawing of *embedded EPAM lid mechanism.*

the blinking mechanism.

Artificial muscle also lend itself to a unique design of ours called the *embedded EPAM lid*. This mechanism would consist of a band of artificial muscle running through the lower edge of the top PMMA eyelid of the prosthesis. This artificial muscle would be fixed at the corners of the eye so that when it contracted, the shortening of the muscle would force the eyelid downward. This design borrows heavily from the function of the human orbicularis occuli muscle as mentioned earlier.

The largest drawback of EPAM technology comes from its low level of availability. Currently only one company (Artificial Muscles Inc.) is in charge of commercializing the product, selling only to other companies or large research groups with large amounts of funding. EPAM cannot be found in a hobby store and there is no sample kit. Being that so few people work with this technology nationwide (for example, no one on the UW Madison Campus works with this technology), it may also prove difficult to get help with our design should we run into any technical problems.

Design Matrix

Table 1: Design Matrix								
	Speed	Noise	Size	Power	Cost	Availability	Endurance	**Total**
Weight	20	16	20	20	4	12	8	**100**
Shape Memory Alloy	3	16	18	4	4	12	2	**59**
Micro Servo	18	10	13	18	3	12	7	**81**
Artificial Muscles (EPAM)	16	14	19	16	0	0	7	**72**

Table 1: Design Matrix; the table indicates the weight of each criterion and the scores for each design possibility

Final Design

Finally, after reviewing all of the relevant criteria through our design matrix (Table 1), the most important of which being speed, power, noise, size and level and availability, our group has chosen the *embedded cord tension mechanism* powered by a micro servo motor as our final design. We chose this design first for its simplicity. The mechanism itself,

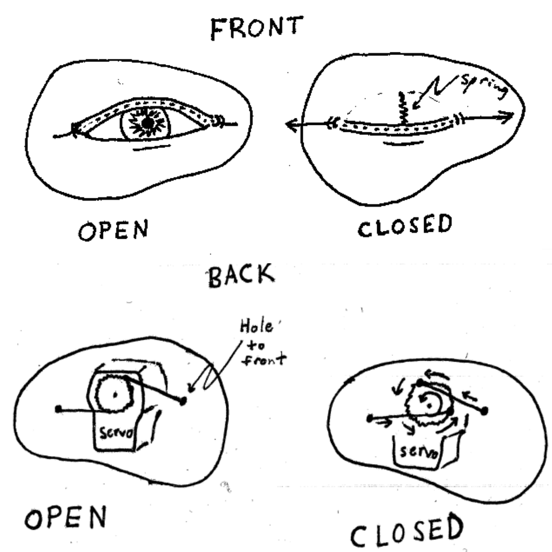

Figure 14: Embedded cord tension mechanism; viewed from both the front and the back.

without regard to power source, replicates the contraction of the lid muscles over the eye using simple mechanical components e.g. cords, tubes, and springs. We chose to power this device with a servo motor because servos are very fast, strong, easily obtainable and are a part of a highly developed market that serves as an excellent resource to find a motor that meets out exact needs and requirements. Another positive attribute of this design is that it allows for a large amount of adaptation and modification concerning its power supply. For instance, though we have decided that a micro servo is the best power supply for our design right now, it can still be switched for another as we become more familiar with the pros and cons of the current technology, or even switched for a completely new technology to be developed in the future. Anything that can create enough tension on the two cords in our mechanism to create a blink can power the *embedded cord tension mechanism.*

Future Work and Conclusions

Now that we have decided on a final design for our blinking orbital prosthesis, we must build a prototype of the *embedded cord tension mechanism.* This prototype will not require a power source as our main goal is to work out the mechanics of the blink. Concerning the power source, we must continue researching fast, quiet and small servo motors to find a motor the meets our specific design specifications. As for other areas of continued research, we must also look further into spring mechanisms to reopen the prosthetic eye once it is closed. This piece of elastic material must be strong enough to pull the eyelid back to its original position, but also not provide so much resistance to the cords that the eye is unable to blink. Lastly, it has come to our attention that the fleshy polymer, PMMA, used to create the lid and surrounding tissue of the prosthetic eye, may be too rigid to construct an eyelid that is actively stretched and un-stretched over millions of blinks. We must therefore research different fleshy polymers that may better accommodate our needs.

Appendix A

Consideration of Electromagents

During our brainstorming process, the idea of using small electromagnets to either attract or repel a permanent magnet in a prosthetic eyelid to create a blink did arise. The magnets are small enough, the smallest having a height and width of about .5 inches. They are also completely silent, which made them a hopeful candidate for one of our designs. Though, when further research was conducted while attempting to purchase an electromagnet to test, it was found that these magnets had no magnetic field at only .5 inches away, let alone any power to attract. The maximum distance of attraction was actually at 1/8 inches. It was also discovered that these magnets were not made to repel objects. They could be modified to do so, but this power to repel would amount to approximately 1/25 of the power of the magnet to attract. For these reasons, electromagnets were ruled out as a possible design element for the blinking orbital prosthesis.

References

[1] "Orbital Prosthesis". The Medical Art Prosthetics Clinic. 3-2-10 <http://www.medicalartprosthetics.com/content.php?page=prostheses&sec=orbital>.

[2] "About Anaplastology". International Anaplastology Association. 3-2-10 <http://www.anaplastology.org/about-anaplastology>.

[3] “Artificial Muscles May Help Patients to Blink.” Medical Device Link. January 25, 2010. Medtech Pulse. <http://www.devicelink.com/mpmn/blog/?p=3402>

[4] “Plastic Surgery Creates Blinking Device.” The Plastic Surgery Channel. Archives of Facial Plastic Surgery.<http://www.theplasticsurgerychannel.com/breaking-news/plastic-surgery-creates-blinking-device.html#more-5283>

[5] Ahn, J., Choung, H. K., Hwang, S. W., Khwarg, S. I. , Kim, N. J., Lee, M. J., and Sung, M. “Frontalis sling operation using silicone rod for the correction of ptosis in chronic progressive external ophthalmoplegia.” *British Journal of Opthamology*. September 11, 2008. Web.

[6] “Gold Weight and Eyelid Spring.” FPI. April 21, 2009. Facial Paralysis Institute. <http://www.facialparalysisinstitute.com/23/Gold%20weight%20and%20eyelid%20springs.html>

[7] Lemke, Bradley, and Mark Lucarelli. Anatomy of the ocular adnexa, orbit, and related facial structures. 2006.

[8] IEEE Industry Applications Magazine March/April 1996, pg 74

[9] Futaba, "Futaba Servos". Hobbico®. 3/2/10 <http://www.futaba-rc.com/servos/>.

[10] Duerig, TW, KN Melton, D Stöckel and CM Wayman. "Engineering Aspects of Shape Memory alloys". ISBN 0-7506-1009-3. London: Butterworth Heinemann, 1990.

[11] "SparkFun Electronics". SparkFun Electronics. 3/1/10 <http://www.sparkfun.com/commerce/product_info.php?products_id=8782>

[12] "Artificial Muscle and Biomimetic Robots." *SRI International*. N.p., n.d. Web. 9 Mar 2010. <http://www.sri.com/robotics/epam.html>.

[13] "Technology." *Artificial Muscles Incorporated*. N.p., n.d. Web. 9 Mar 2010. <http://www.artificialmuscle.com/technology/epam.php>.

[14] Pelrine, Ronald E., Roy D. Kornbluh, and Jose P. Joseph. "Electrostriction of polymer dielectrics with compliant electrodes as a means of actuation." *Sensors and Actuators*. A.64 (1998): 77-85. Print.

Appendix B – Product Design Specifications

Function:

Patients of any gender or age may experience the loss or absence of their eye due to some type of accident, genetic defect, or disease. Prosthetic eyes are made to help these people have a greater sense of confidence and positive self-image. Our goal is to create an improved orbital prosthesis which can restore a truly natural appearance. We intend to accomplish this by designing a device that enables the prosthetic eye to blink. Our design will focus on developing a model that portrays this blinking mechanism.

Client requirements:

- Costs for the project should be under $500.
- Create a mechanism to cause the prosthetic eye to blink.
- The mechanism should be contained inside of the cavity of the globe of the eye.
- Must be damped in order to minimize sound and vibrations.
- Must be as aesthetically pleasing.
- Blink time must be realistic.

Design requirements:

The model of the orbital prosthesis will only be used in presentation settings, to demonstrate the blinking mechanism. However, we will still take into consideration the requirements for a fully functional orbital prosthesis.

1. Physical and Operational Characteristics

a. *Performance requirements*:
- Model: It would be used once a week for 10-20 minutes at a time.
- Fully Functional: Must be equipped for continual daily use, 16-18 hours a day for at least one year.

b. *Safety*:
- Model: Must have proper electrical wiring, in order to prevent electric shock to the presenter.
- Fully Functional: Must be made of easily sanitized materials that are biocompatible.

c. *Accuracy and Reliability*:

- Model: Must blink when prompted, on every occasion. Must be able to blink at a rate of 300-400 milliseconds per blink.
- Fully Functional: Must be synchronized with the blinking of the other functional eye.

d. *Life in Service*:
- Model: Reusable; must be usable 300 times a year, ideally for multiple years.
- Fully Functional: Must be operational for daily use for at least a year, with only minor maintenance.

e. *Shelf Life*:
- Model: The shelf life of or design would be the shelf life of the motor that we use.
- Fully Functional: Skin mimicking gelatin may need to be replaced after extended use. Batteries might also need to be replaced at regular intervals.

f. *Operating Environment*:
- Model: The device will be used in an open environment and as such will not be as limited by the size requirements of an eye socket.
- Fully Functional: The orbital prosthesis will be used within a patient's eye socket. The prosthesis will be limited by the small volume available and also needs withstand the conditions of the human body.

g. *Ergonomics*:
- Model: The device should be easily operated by a single presenter.
- Fully Functional: The device must be easily removable, chargeable, and sterilized.

h. *Size*:
- Model: The maximum size of the prosthesis should be the size of the human eye socket.
- Fully Functional: The fully functional prosthesis should be no bigger than the model.

i. Weight:
- Model: Not an issue. Reasonable weight for one person carrying (3-5 lb.)
- Fully Functional: Must be comfortable for patient use.

j. *Materials*:
- Model: Prosthetic eyes now are made out of PMMA, Poly(methyl methacrylate) and Acrylic. Our device will use these materials, a light weight metal and/or plastic for the motor and elastic polymer for the closing mechanism.
- Fully Functional: Any materials that would come in contact with the patient's skin will need to be non-allergenic or coated with a material to prevent any allergic reaction.

k. *Aesthetics, Appearance, and Finish*:
- Model: It should be aesthetically pleasing. The mechanism should be completely contained within the globe the prosthesis with the exception of an actuating device (ex. switch or button).

- Fully Functional: The goal is to make a more realistic prosthesis, so a human-like appearance is what the product should display.

2. Production Characteristics

a. *Quantity*: 1 deliverable.

b. *Target Product Cost*: Under $500, additional funding will be available if specialized materials need to be ordered.

3. Miscellaneous

a. *Standards and Specifications*: We must adhere to the medical device regulations established by the U.S. government and the World Health Organization. We must also make a device that satisfies our client's standards.

b. *Customer/Patient related concerns*: None for the model. However, the fully functional prosthesis would need to be small enough to fit comfortably into the patient's eye socket, quiet, capable of performing with minimal vibrations, and easy to disinfect regularly.

d. *Competition*: There have been multiple attempts and possibly successes at a blinking orbital prosthesis. However, at least here in the Madison area these prosthetics are not available to the general public for use.